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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,333	07/26/2001	Franco Pamparana	101615-00012	5701

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EXAMINER
HENLEY III, RAYMOND J

ART UNIT	PAPER NUMBER
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/869,333	Franco Pamparana
Examiner	**Art Unit**
Ray Henley	1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Dec 16, 2002*.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-29* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☒ Interview Summary (PTO-413) Paper No(s). 8
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

CLAIMS 1-29 ARE PRESENTED FOR EXAMINATION

Applicant's Response filed December 16, 2002 has been received and entered into the application. Accordingly, in order to consider originally filed claims 1-29 on the merits (as explained in Applicant's Response), the previous Office action dated March 14, 2002 and re-mailed November 22, 2002 is hereby vacated. See also the attached Interview Summary Record wherein the conversion conducted on December 11, 2002 is summarized.

As per Applicant's Preliminary Amendment filed July 26, 2001, claims 1, 3-5, 9-11, 15, 21, 26 and 29 have been amended.

An action respecting claims 1-29 on the merits follows.

Claim Objections

Claims 18-29 are objected to because of the following informalities:

In claims 18 and 27, line 1, the expression "who is survivor" should read ---who is a survivor---.

In claims 19-23, 25, 26, 28 and 29, line 1, "A method" should read ---The method---.

In claim 23, line 1, the term "ration" should read ---ratio---.

In claim 24, line 1, the term "morality" should read ---mortality---.

In claim 25, line 1, the term "contention" should read either as ---content--- or ---concentration---.

Appropriate correction is required.

Claim Rejection

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 8 provide for the use of essential fatty acids in the preparation of a medicament which is useful for a therapeutic purpose, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 1-11 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for

example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Insofar as the subject matter intended to be patented in claims 1-11 is unclear to the Examiner given the above, the claims will not be further treated on the merits.

Claim Rejection - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12-29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for preventing mortality or sudden death caused by the reoccurrence of a myocardial infarction (present specification at page 2, lines 11-15) in patients who have suffered a myocardial infarction, does not reasonably provide enablement for preventing mortality or sudden death in general in patients who have suffered a myocardial infarction. Such would encompass death and/or mortality events which may or may not be preventable, e.g., due to Alzheimer's disease or otherwise be due to natural causes other than a reoccurrence of a myocardial infarction. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Wands, 8

USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors as applied to the present application (see below)are weighed, it is the examiner's position that the present specification would only enable the skilled artisan to prevent mortality or sudden death caused by the reoccurrence of a myocardial infarction (present specification at page 2, lines 11-15) in patients who have suffered a myocardial infarction.

(1) The nature of the invention.

The claims set forth methods for the prevention or mortality or sudden death in patients who have survived myocardial infarction in which essential fatty acids are administered.

(2) The state of the prior art.

The prior art recognizes that essential fatty acids of the type claimed may be employed for the prevention of sudden death or mortality caused by reoccurrence of a myocardial infarction in patients who have suffered myocardial infarction. See Leaf et al. (U.S. Patent No. 5,760,081) [the entire document is believed to be relevant].

(3) The relative skill of those in the art.

The relative skill of the those in the art is high.

(4) The predictability or unpredictability of the art.

The unpredictability of the pharmaceutical chemistry/medical art is very high.

As an example of the unpredictability in the art, the Examiner points to two very well known therapeutic agents, namely quinine and quinidine. Quinine and quinidine differ from each other only in that they are mirror images of each other. However, the therapeutic activity of each is quite distinct. Namely, quinine is effective for reducing a fever or as an anesthetic, while quinidine finds application as a cardiac suppressant.

Also, respecting the objective of preventing mortality or sudden death in general in any patient population, the Examiner can find no reference which would support a contention that objective was known or expected by the skilled artisan using any therapeutic means.

(5) The breadth of the claims.

The claims are not limited to mortality or sudden death caused by the reoccurrence of a myocardial infarction in a patient who had previously suffered a myocardial infarction, but rather recite "mortality" and "sudden death" in general.

(6) The amount of direction or guidance presented.

The specification provides specific and adequate directions for preventing mortality or sudden death caused by the reoccurrence of a myocardial infarction (present specification at page 2, lines 11-15) in patients who have suffered a myocardial infarction.

(7) The presence or absence of working examples.

Applicant at page 6 of the present specification merely shows compositions useful for preventing mortality or sudden death caused by the reoccurrence of a myocardial infarction in patients who have suffered a myocardial infarction. No data is supplied showing clinical data resulting from the administration of such compositions for preventing mortality or sudden death caused by the reoccurrence of a myocardial infarction in patients who have suffered a myocardial infarction.

(8) The quantity of experimentation necessary.

Because of the unpredictability of the art, see (4) above, it is believed that undue experimentation would be necessary to practice the invention of the scope claimed.

Accordingly, for the above reasons, claims 12-29 are deemed to be properly rejected under 35 U.S.C. 112, first paragraph.

Claim Rejection - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 12-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leaf et al. (U.S. Patent No. 5,760,081) in view of Derwent Abstract 1992-085863 (Nippon Oils & Fats Co. Ltd., hereinafter referred to as "Nippon"), the former reference having been made of record by the Examiner (see form PTO-892 signed on March 13, 2002) and the latter being supplied by applicant (IDS filed November 15, 2001, reference "AO").

Leaf et al. teach methods for the prevention of imminent ventricular fibrillation which comprises the administration, which may be by intravenous infusion, of a composition which comprises eicosapentaenoic acid (EPA), docosahexaenoic acid (DHA) or a mixture of EPA and DHA (see the abstract). At column 1, line 18, it is highlighted that ventricular fibrillation can lead to sudden death. At column 1, lines 21-24, it is highlighted that the high incidence of recurrent ventricular fibrillation and sudden death in survivors of cardiac arrest underscores the need for an effective approach to prophylactic treatment in these patients. At column 5, lines 21-22, the patentees teach the use of ethyl esters of EPA and/or DHA for the above purposes.

The difference between the above and applicant's claimed subject matter lies in that Leaf et al. fail to highlight oral administration and also fail to highlight the presently claimed amounts/proportions.

However, the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains because Nippon teaches that compositions containing 90% by weight of the ethyl ester of DHA

may be administered not only intravenously, but orally as well to a patient for the purpose of inhibiting ventricular fibrillation. Insofar as Leaf et al. teach that EPA and/or DHA can be used for that purpose, it is believed the skilled artisan would have been imbued with a reasonable expectation that the teachings of Nippon would equally apply to EPA. Also, given the combined teachings of both Leaf et al. and Nippon, it is believed that the skilled artisan would have been imbued with at least a reasonable expectation that invention of Leaf et al. could be successfully practiced if the active ingredients were to be administered orally. As for the specific amounts/proportions of ingredients as presently claimed by applicant and not highlighted in the prior art, such would have been obvious because the determination of the optimum ingredient amounts/proportions to employ would have been a matter well within the purview of the skilled artisan and would have been expected to vary depending upon the physical characteristics of the patient, severity of the condition and the presence/absence of other factors which would affect the bioavailability of the drugs, i.e., presence/absence of renal disease or liver disease.

Accordingly, for the above reasons, the claims are deemed to be properly rejected/objected to and none of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ray Henley whose telephone number is (703) 308-4652.

RAYMOND HENLEY, III
PRIMARY EXAMINER
GROUP 1600

Henley; rjh
February 22, 2003